



National Adult
and Influenza
Immunization
Summit

The Universal Influenza Immunization Recommendation in the United States



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Disclosures

- I have no conflicts of interest to declare

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Why seasonal influenza programs are critical to pandemic preparedness

“By failing to prepare, we are preparing to fail”
- Benjamin Franklin

- Leaves us vulnerable during times of crisis when the ability to reach 250 million adults with vaccines/medications is crucial
- Our failure to successfully immunize adults in healthy times predicts our failure to immunize them in times of crisis...

Evolution of seasonal influenza vaccination policy in the United States

Pre-2000	<p>Persons aged 65 or older</p> <p>Persons with chronic medical conditions that make them more likely to have complications of influenza</p> <p>Pregnant women in the second or third trimester</p> <p>Contacts (household and out of home caregivers) of the above groups</p> <p>Health care workers</p>
2000	Adults 50 and older
2004	<p>Children aged 6 through 23 months</p> <p>Contacts (household and out of home caregivers) of children aged 0 through 23 months</p> <p>Women who will be pregnant during influenza season</p>
2006	<p>Children aged 6 through 59 months</p> <p>Contacts (household and out of home caregivers) of children aged 0 through 59 months</p>
2008	All children 6 months through 18 years, if feasible
2009	All children 6 months through 18 years
2010	All persons 6 months and older

The United States has a universal recommendation for influenza immunization

- Annual influenza vaccination is recommended for ALL persons aged 6 months of age or higher, unless there is a medical contraindication

Influenza Recommendations in 2008

- Children aged 6–23 months;
- Children aged 24–59 months
- Children and adolescents (aged 6 months–18 years) who are receiving long-term aspirin therapy and, therefore, might be at risk for experiencing Reye syndrome after influenza virus infection;
- Women who will be pregnant during the influenza season;
- Adults and children who have chronic disorders of the pulmonary or cardiovascular systems, including asthma (hypertension is not considered a high-risk condition);
- Adults and children who have required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus [HIV]);
- Adults and children who have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration;
- Residents of nursing homes and other chronic-care facilities that house persons of any age who have chronic medical conditions;
- Persons aged 50-64 year;
- Persons aged ≥ 65 years;
- Healthy household contacts and caregivers of children 0-59 months of age and persons at high risk for severe complications from influenza; and,
- Health care workers.



Risk Factors for Complications of or Severe Illness with 2009 H1N1 Virus Infection

Table 1. Risk Factors for Complications of or Severe Illness with 2009 H1N1 Virus Infection.*

Risk Factor	Examples and Comments
Age <5 yr	Increased risk especially for children <2 yr of age; highest hospitalization rates among children <1 yr
Pregnancy	Risk of hospitalization increased by a factor of 4 to 7, as compared with age-matched nonpregnant women, with highest risk in third trimester
Chronic cardiovascular condition	Congestive heart failure or atherosclerotic disease; hypertension shown to be an independent risk factor
Chronic lung disorder	Asthma or COPD, cystic fibrosis
Metabolic disorder	Diabetes
Neurologic condition	Neuromuscular, neurocognitive, or seizure disorder
Immunosuppression	Associated with HIV infection, organ transplantation, chemotherapy, or corticosteroids, or malnutrition
Morbid obesity†	Suggested but not yet proved to be an independent risk factor for complications requiring hospitalization and possibly for death
Hemoglobinopathy	Sickle cell anemia
Chronic renal disease	Renal dialysis or end-stage renal disease
Chronic hepatic disease	Cirrhosis
Long history of smoking	Suggested but not yet proved to be an independent risk factor
Long-term aspirin therapy in children	Reye syndrome; drugs containing salicylates should be avoided in children with influenza
Age ≥65 yr	Increased hospitalization rate but lowest rate of infection

* COPD denotes chronic obstructive pulmonary disease, HIV human immunodeficiency virus, and ICU intensive care unit.
 † Morbid obesity is defined as a body-mass index (the weight in kilograms divided by the square of the height in meters) of 40 or more.

PLUS - Native Americans/Alaskan Americans!

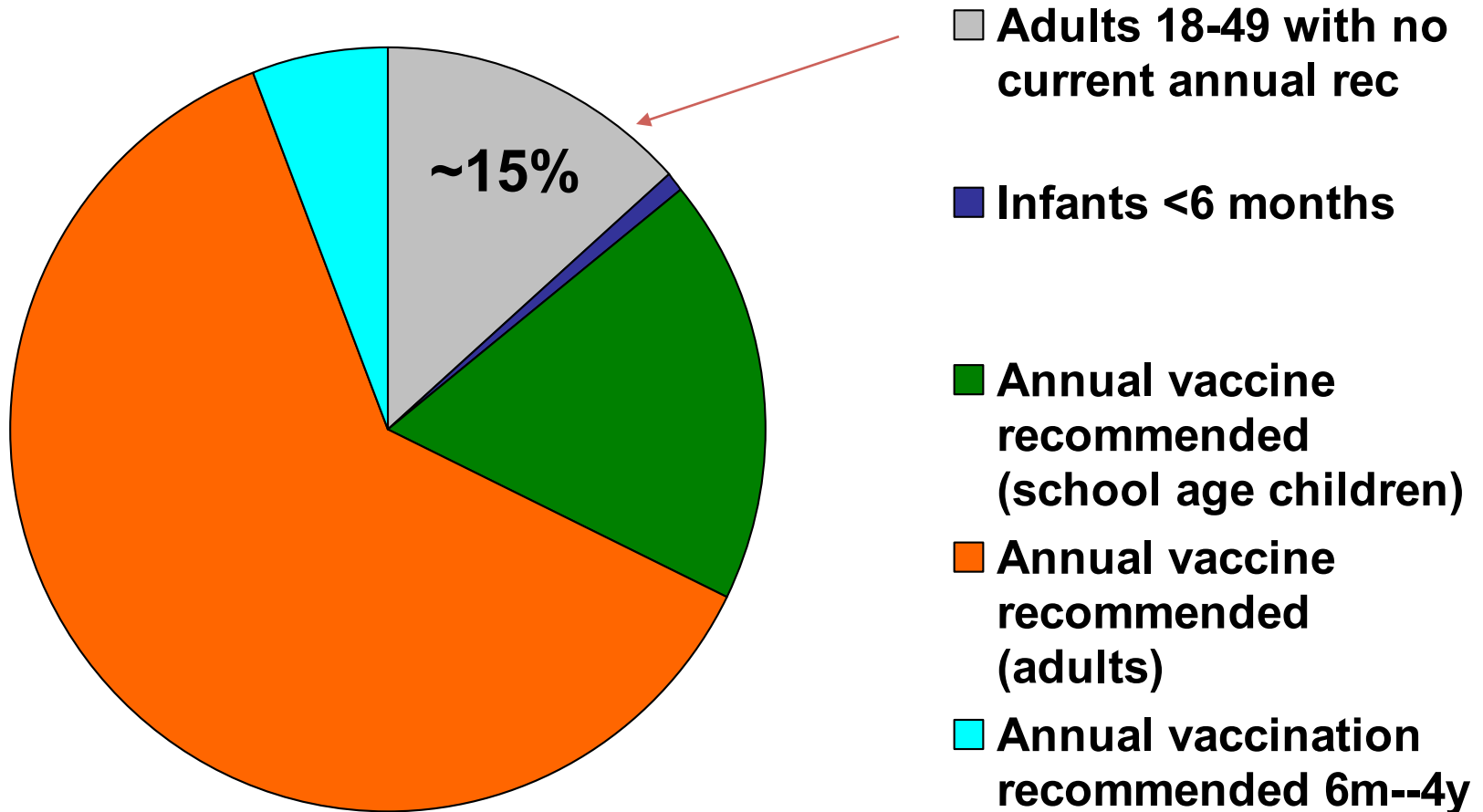


Risk-based Recommendations have Limitations

- Complicated!
- Risk groups can be difficult to remember
 - In 2010, there were at least 16 specific influenza vaccination target groups
- Results in multiple missed opportunities to vaccinate as it's harder for health care providers to identify patients by risk than by age
- More difficult for patients to self-identify based on risk conditions
 - Many patients simply do not believe they are at risk.
- Coverage levels among the target groups vary, but in general are low.



US Population Groups by Vaccination Recommendation Status



Rationale: Recommendation to vaccinate all people ages 6 months or older

- Annual influenza vaccination is a safe and effective prevention measure that provides a potential benefit for people in all age groups
- Morbidity and mortality occurs in all age groups, including among adults aged 19-49
- Already 50% of healthy adults had a recommendation, and 85% overall
- Some persons who have influenza complications
 - have no previously identified risk factors
 - have risk factors but are unaware that they should be vaccinated
 - might be at risk due newly identified risk factors, such as morbid obesity or race/ethnicity

Rationale: Recommendation to vaccinate all people ages 6 months or older

- A recommendation that all people ages 6 months or older receive an annual influenza vaccination
 - eliminates the need to determine whether each person has an indication for vaccination
 - emphasizes the importance of preventing influenza across the population spectrum
 - reduces potential barriers to increasing the number of persons protected from influenza, including lack of awareness about vaccine indications among persons at higher risk for influenza complications and their close contacts



Lessons Learned from Progress to Universal Recommendation

- Influenza causes substantial morbidity and mortality in many different populations; vaccination is cornerstone of influenza prevention
- Vaccine efficacy is only one of many considerations in making policy decisions
 - Burden of disease is critical
 - What are the efficacy outcomes that are important? Just incidence?
 - Absolute as well as relative prevention is important
 - Practical considerations
- Need a stable vaccine supply; not necessarily adequate
- The landscape of influenza vaccine development is rapidly evolving; policymakers will also need to be flexible

Lessons Learned from Progress to Universal Recommendation

BUT...

Lessons Learned from Progress to Universal Recommendation

- Policy change is slow and may be difficult to accomplish in the absence of a perceived external threat
 - 2009 H1N1 provided that impetus in the United States
- Public health policy, like medicine, must always be practiced in an environment where you have less data than you would like
- Policy can be made before absolute clarity is achieved
- Recommendations drive infrastructure development – not the other way around
- Change is difficult...fear is a strong disincentive



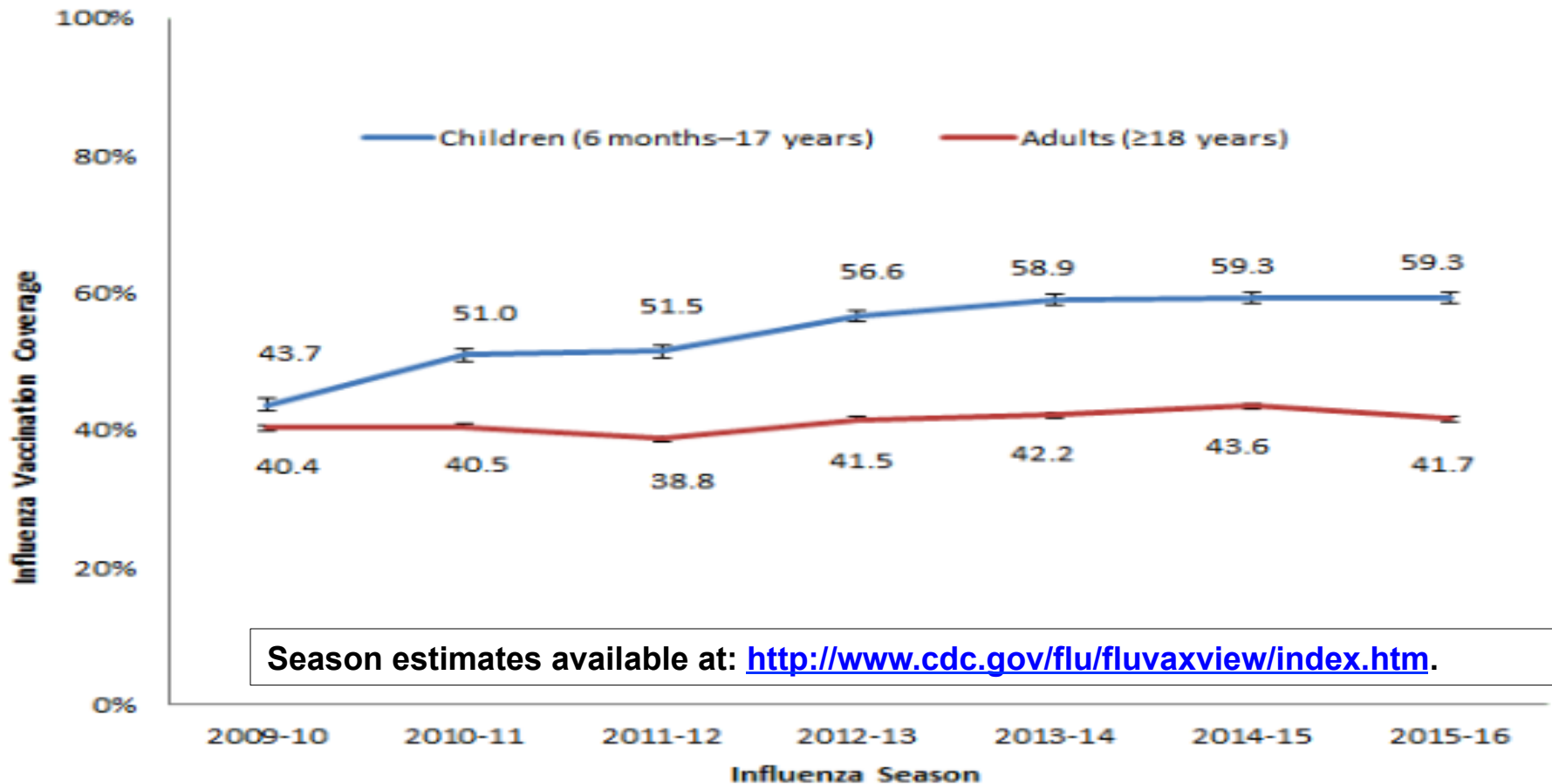
IMPLEMENTATION AND EVALUATION



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Coverage by Age: 2009-10 thru 2015-16 Seasons (universal recommendation implemented in 2010)

Figure 1. Seasonal Flu Vaccination Coverage by Age Group and Season, United States, 2009–2016



Error bars represent 95% confidence intervals around the estimates.

The 2009-10 estimates do not include the influenza A (H1N1) pdm09 monovalent vaccine.

Starting with the 2011-12 season, adult estimates reflect changes in BRFSS survey methods: the addition of cellular telephone samples and a new weighting method.

Adjusted vaccine effectiveness estimates for influenza seasons, 2005-2016

Influenza Season [†]	Study Site(s)	No. of Patients [‡]	Adjusted Overall VE (%)	95% CI
2004-05	WI	762	10	-36, 40
2005-06	WI	346	21	-52, 59
2006-07	WI	871	52	22, 70
2007-08	WI	1914	37	22, 49
2009-10	WI, MI, NY, TN	6757	56	23, 75
2010-11	WI, MI, NY, TN	4757	60	53, 66
2011-12	WI, MI, PA, TX, WA	4771	47	36, 56
2012-13	WI, MI, PA, TX, WA	6452	49	43, 55
2013-14	WI, MI, PA, TX, WA	5990	51	43, 58
2014-15	WI, MI, PA, TX, WA	9329	23	14, 31
2015-16	WI, MI, PA, TX, WA	3919	59	44, 70
2016-17*	WI, MI, PA, TX, WA	2073	48	37, 57

- Case-control
- PCR-confirmed MAARI
- Focus on ACIP recommended groups
- Controls – tested negative for influenza

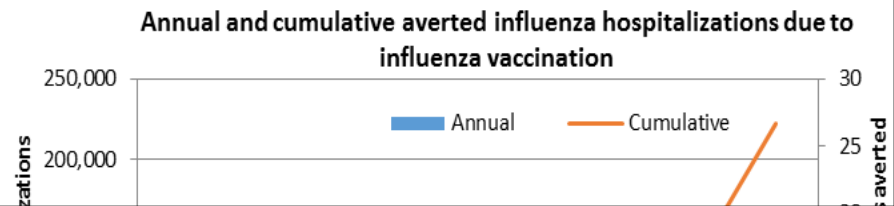
*interim estimates,
NAIIS, May 2017



CDC's Influenza Vaccine Program Effectiveness Summary of findings

Each year between 2005 - 2013, influenza vaccine prevented:

- 1.1 – 9.5 M cases
- 440,000 – 4 M outpatient visits
- 7,700 – 89,000 hospitalizations
- 2.5 – 25 million averted



- Uses simple model
- Illness/outcomes averted may be an easier and more meaningful way to communicate the value of the vaccine?
- Estimates can be updated annually
- Can apply economic values to the model; estimate effect of program changes, etc.

Another way to look at vaccine effectiveness – negative outcomes averted

the **benefits** of **flu vaccination** 2016-2017

The estimated number of flu **illnesses prevented** by flu vaccination during the 2016-2017 season:

5.3 million,

about the population of the Atlanta metropolitan area.



The estimated number of flu **medical visits prevented** by vaccination during the 2016-2017 season:

2.6 million,

or more than the number of students in all K-12 schools in Florida.



The estimated number of flu **hospitalizations prevented** by vaccination during the 2016-2017 season:

85,000,

or more than the number of hospital beds in California and Oregon.



DATA: Influenza Division program impact report 2016-2017, <https://www.cdc.gov/flu/about/disease/2016-17.htm>.

get vaccinated
www.cdc.gov/flu



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Potential Policy Challenges going Forward

- Converting recommendations to “evidence-based” structure
 - What’s the evidence base for that remaining 15%?
 - Is it necessary or can policy decision be enough?
- Determining the role of new vaccines
 - high-dose (or adjuvanted) preference in elderly?
 - LAIV vs. TIV
 - Quadrivalent vs TIV
 - Adjuvanted vaccines
 - H5 vaccines for high-risk persons

Messaging Challenges of the Universal Recommendation

- Universal recommendation adds challenges for communications regarding populations that must be vaccinated
 - children, adults w/ chronic disease, elderly, pregnant
- A strong, consistent, and simple message has begun to embed universal recommendation in the mindset of the public
 - Acknowledge where the science is and where policy decision making began
 - Leverage concept of protecting vulnerable by vaccinating all
- Emphasize that vaccine effectiveness is not simply about prevention of infection
- Tried to not caveat the universal message too much as that would undermine the universal recommendation
 - No other universally recommended vaccine has such caveats
- Needed to be unified in messages to the provider and the public



Summary

- US recommends influenza vaccine for all >6 months
- Expansion to universal recommendations was a long process
 - Started with risk-based approach
 - Incremental expansion to additional risk groups using evidence of disease burden
 - Augmented by age-based recommendations
 - Policy development can occur even if not all the science is in

Summary (cont.)

- Vaccine acceptance remains too low in some age groups
 - Under-appreciation of risk, and risk factors (for both vaccine and for the disease itself)
 - Quality of life and negative impacts of influenza under-appreciated
- Robust programs exist to estimate the benefits of vaccines
- Vaccine approval and policy development process transparent and trusted by providers
- Aggressive communications program critical to increasing coverage
 - Must meet the public where they are



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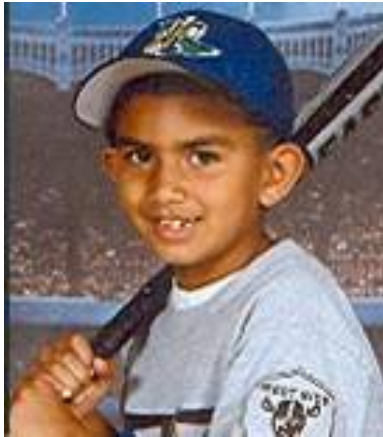


Amanda, died at age 4½ yrs from influenza

Why do we immunize against influenza?



Breanne, died at age 15 mos from influenza complications



Lucio, died at age 8 yrs from influenza complications



Alana, died at age 5½ yrs from influenza



Barry, a veteran fire-fighter, died at age 44 yrs from influenza

Slide Courtesy of Families Fighting Flu



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**Thank You
for your
attention!**



<http://go>



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